JUN 19 2006

K061041

510(k) Summary

Manufacturer:	US Spine 3600 FAU Blvd., Suite 101 Boca Raton, FL 33431
Submitted By:	Richard Jansen, Pharm. D. Silver Pine Consulting 13540 Guild Ave. Apple Valley, MN 55124 Phone 952-431-5999 Fax 952-432-3245 richj@s-pineconsulting.com
Proprietary Name:	US Spine Facet Fixation System
Classification Name:	Appliance, Fixation, Spinal
Common/Usual Name:	Facet Screw Spinal Device System
Classification:	Class II
Predicate Devices:	DISCOVERY Facet Screw (K012773) Triad Facet Screw System (K020411) Oasys Bone Screw (K031657) Townley Transfacet/Intrapedicular Screw (K994308)
Device Description:	The US Spine Facet Fixation System consists of two implantable components, the screw in various lengths and an optional washer. Both components are made from implant grade wrought Titanium 6-Aluminum 4-Vanadium (Ti6Al4V) alloy.
Indications for Use:	The Facet Fixation System is indicated for the posterior surgical treatment of any or all of the following at the C2-S1 spinal levels: 1) Trauma, including spinal fractures and/or dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) degenerative disc disease (ddd) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with instability.

When properly used, facet screws will provide temporary stabilization as an adjunct to spinal bone grafting processes.

Performance Data: Biomechanical testing, including static and fatigue 3-Point Bend Testing and Cantilever Testing were performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2006

US Spine
% Silver Pine Consulting
Rich Jansen, Pharm.D.
13540 Guild Avenue
Apple Valley, Minnesota 55124

Re: K061041
Trade/Device Name: Facet Fixation System
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Class II
Product Code: MRW
Dated: May 24, 2006
Received: May 26, 2006

Dear Mr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restoration
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K061041

Device Name: Facet Fixation System

Indications for Use:

The Facet Fixation System is indicated for the posterior surgical treatment of any or all of the following at the C2 to S1 (inclusive) spinal levels: 1) Trauma, including spinal fractures and/or dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) degenerative disc disease (ddd) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with instability.

When properly used, facet screws will provide temporary stabilization as an adjunct to spinal bone grafting processes.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061041